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ATTORNEY DOCKET NO. CONFIRMATION NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE PF-0698 USN 4335 Jennifer L Hillman 10/23/2001 10/019,495 EXAMINER 06/30/2004 22428 7590 BASI, NIRMAL SINGH FOLEY AND LARDNER SUITE 500 PAPER NUMBER ART UNIT 3000 K STREET NW WASHINGTON, DC 20007 1646 DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		<b>Application No.</b> 10/019,495	Applicant(s) HILLMAN ET AL.
	Office Action Summary	Examiner	Art Unit
		Nirmal Basi, Ph.D.	1646
Period fo	The MAILING DATE of this communication apor Reply	ppears on the cover sheet wit	h the correspondence address
THE - Exte after - If the - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPIMAILING DATE OF THIS COMMUNICATION ensions of time may be available under the provisions of 37 CFR 1 SIX (6) MONTHS from the mailing date of this communication. The period for reply specified above is less than thirty (30) days, a result of period for reply is specified above, the maximum statutory period reply within the set or extended period for reply will, by staturely received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply within the statutory minimum of thirty will apply and will expire SIX (6) MONT te, cause the application to become ABA	eply be timely filed  (30) days will be considered timely.  FHS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133).
Status			
1)[🛛	Responsive to communication(s) filed on 20	<u>May 2004</u> .	
2a)[_	This action is <b>FINAL</b> . 2b) ☐ Th	is action is non-final.	
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
	closed in accordance with the practice under	Ex parte Quayle, 1935 C.D.	11, 453 O.G. 213.
Disposit	ion of Claims		
4)🖂	Claim(s) <u>1-15,17,18,20,21 and 23</u> is/are pend	ding in the application.	
	4a) Of the above claim(s) is/are withdr	awn from consideration.	
5)	Claim(s) is/are allowed.		
6)	Claim(s) is/are rejected.		
7)	Claim(s) is/are objected to.		
8)🖂	Claim(s) <u>1-15,17,18,20,21 and 23</u> are subjec	t to restriction and/or election	n requirement.
Applicat	ion Papers		
9)[	The specification is objected to by the Examir	ner.	
10)	The drawing(s) filed on is/are: a) ac	cepted or b) objected to b	y the Examiner.
	Applicant may not request that any objection to the	e drawing(s) be held in abeyand	ce. See 37 CFR 1.85(a).
	Replacement drawing sheet(s) including the corre	ction is required if the drawing(	s) is objected to. See 37 CFR 1.121(d).
11)	The oath or declaration is objected to by the E	Examiner. Note the attached	Office Action or form PTO-152.
Priority (	under 35 U.S.C. § 119		
12)	Acknowledgment is made of a claim for foreig	n priority under 35 U.S.C. §	119(a)-(d) or (f).
a)	☐ All b)☐ Some * c)☐ None of:		
	1. Certified copies of the priority documer	nts have been received.	
	2. Certified copies of the priority documen	nts have been received in Ap	oplication No
	3. Copies of the certified copies of the pri	ority documents have been	received in this National Stage
	application from the International Bure	au (PCT Rule 17.2(a)).	
* 5	See the attached detailed Office action for a lis	st of the certified copies not r	eceived.
Attachmen	ut(s)		
	ce of References Cited (PTO-892)	4) Interview Su	ummary (PTO-413)
2) 🔲 Notic	ce of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)	)/Mail Date
3) L Infor	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08	3) 5) ☐ Notice of Int	formal Patent Application (PTO-152)

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### **DETAILED ACTION**

## Election/Restrictions

#### PART A: TYPES OF INVENTIONS

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group A-I, claim(s) 1-6, 8, 10-11, 15, drawn to polypeptides, pharmaceutical compositions comprising the polypeptide, polynucleotides encoding the same, cells transformed with the polynucleotides, and methods of producing the encoded polypeptides.

Group A-II, claim(s) 7, drawn to a transgenic organism.

Group A-III, claim(s) 9, drawn to an antibody.

Group A-IV, claim(s) 12-14, drawn to methods for detecting a target polynucleotide.

Group A-V, claim(s) 17 and 20, drawn to methods for identifying agonists and antagonists.

Group A-VI, claim(s) 18 and 21, drawn to pharmaceutical compositions comprising agonists or antagonists.

Group A-VII, claim(s) 23, drawn to a method for screening a compound for effectiveness in altering expression of a target polynucleotide.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of Group I is the recited polypeptide and polynucleotide. The related first claimed method of making and using the first claimed products, i.e., the method of using the polynucleotides to make the encoded protein, is included in Group I because the PCT rules provide for the examination of the first claimed product, first claimed method of making the product, and first claimed method of using the product in one application.

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However, Groups II, III and VI are directed to additional products wherein the products have additional features (e.g., the animal) or different structures (e.g., the antibody or agonist/antagonist) such that separate searches would have to be conducted for these products. The PCT rules do not provide for the examination of multiple [products in one application. Similarly, the methods of Groups IV and V involve method steps that are distinct from the method of Group I, requiring significant additional searching. The PCT rules do not provide for the examination of multiple methods in a single application.

### **PART B: TYPES OF SEQUENCES**

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group B-I, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 1.

Group B-II, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 2.

Group B-III, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 3.

Group B-IV, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 4.

Group B-V, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 5.

Group B-VI, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 6.

Group B-VII, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 7.

Group B-VIII, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 8.

Group B-IX, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 9.

Group B-X, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 10.

Group B-XI, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 11.

Group B-XII, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 12.

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Group B-XIII, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 13. Group B-XIV, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 14. Group B-XV, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 15. Group B-XVI, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 16. Group B-XVII, claim(s) 1-15, 17, 18, 20, 21 and 23 as they relate to SEQ ID NO: 17.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed product is the sequence of SEQ ID NO: 1. None of the other sequences share this special technical feature, as each defines a separate contribution over the art.

IN ORDER TO BE FULLY RESPONSIVE, APPLICANT MUST CHOOSE ONE GROUP FROM A-I THROUGH A-VII **AND** ONE GROUP FROM B-I THROUGH B-XVII.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi, Ph.D. whose telephone number is (571) 272-0868.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ECK** 

ELIZABETH KEMMERER PRIMARY EXAMINER

Elizabeth C. Kenneur